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**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/163,089 09/29/98 MCKENZIE

I 4102-1

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SHERIDAN ROSS PC
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HM12/0605

EXAMINER

OGIHARA, N

ART UNIT

PAPER NUMBER

1631

10

DATE MAILED:

06/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.		Applicant(s)	
	09/163,089		MCKENZIE ET AL.	
	Examiner		Art Unit	
	Nancy Ogiwara		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 14) <input type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 19) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 1-69 are pending in the instant application. Applicant's election, with traverse, of Group I, claims 1-51, directed to a method to induce an immune response by administering a population of cells, in Paper No. 12 filed 04/06/00 is acknowledged.

The traversal is on the ground(s) that the examiner did not satisfy the requirements for restriction between patentably distinct inventions, stating that the Examiner has not established that examining the inventions in a single application will create a serious burden on the PTO. Applicant further argues that Groups I and III are so closely related as to be capable of examination together, and that a thorough search of Group I would be sufficient to examine the claims of Group II.

Applicant's arguments have been fully considered, but they are not persuasive for the following reasons: Groups I-III, as set forth in the restriction requirement, are independent and distinct, as Invention I is drawn to a composition comprising cells and an antigen, while Invention III is drawn to a therapeutic compound which does not comprise cells. Cells and therapeutic (i.e. chemical) compounds are in separate biological classifications, and while their searches may be overlapping, there is no reason to believe that the searches would be co-extensive. Furthermore, the composition of Invention I is separate and distinct since it can be used in a materially different process such as identifying mannose receptor ligands in in vitro assays. Therefore, because their status in the art is divergent, Groups I-III are separate and distinct for the reasons given above, and there would be a serious burden placed on the examiner from further searching and consideration if the restriction were not required.

Examiner has considered Applicant's response to the election, however, the claims are going to be re-restricted with additional elections of species in the following way. Applicant may submit further arguments in the response to the restriction requirement of this action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-51, drawn to mannose receptor bearing cells, classified in class 435, subclass 325.1. If this group is elected, 3 elections of species are required.

1st species election is required for the mannose used: electing either A) oxidized mannose or B) partially reduced mannose;

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2nd species election is required to elect either (A) cells without a biological response modifier, or (B) cells with a biological response modifier;

3rd election of species is required to elect an antigen as listed in Claim 12.

- II. Claims 52-60, drawn to a method of inducing an immune response, classified in class 424, subclass 185.1. If this group is elected, 3 elections of species are required.

1st species election is required for the mannose used: electing either A) oxidized mannose or B) partially reduced mannose;

2nd species election is required to elect either (A) cells without a biological response modifier, or (B) cells with a biological response modifier;

3rd election of species is required to elect an antigen as listed in Claim 12.

- III. Claims 61-69, drawn to a therapeutic compound, classified in class 514, subclass 23. If this group is elected, an election of species is required to elect an antigen as listed in Claim 65

The inventions are distinct, each from the other because of the following reasons:

SPECIES REQUIREMENT

For Group I, applicant must elect a mannose species: (A) oxidized mannose or (B) partially reduced mannose.

For Group I, applicant must elect: (A) cells with a biological response modifier or (B) cells without a biological response modifier.

For Group I, applicant must elect an antigen selected from those listed in Claim 12.

Each of the species are physically and functionally distinct chemical entities with different sequences coding for different structural and biological properties and activities.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3-21, 23-34, 36-45, 47-52, and 54-60 are generic for mannose species. Claims 1-7, 12-23, 26, 38-47, and 52-69 are generic for the biological response modifier election of species. Claims 1-12, 17-19, 20-35, 39-58, and 61-65 are generic for the antigen.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the mannose receptor bearing cell can be used to identify mannose receptor ligands in *in vitro* assays. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

Inventions I and III are separate and distinct, as they are drawn to differing compositions of matter. Invention I is drawn to a composition comprising cells and an antigen, while Invention III is drawn to a therapeutic compound which does not comprise cells. The inventions have different components and method steps of preparation. As such the Inventions would require searching in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

Inventions II and III are separate and distinct as the composition of Invention III is not sufficient for use in the methods of Invention II. As such the search for Invention II would require searching in additional and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Ogihara whose telephone number is (703) 308-9363. The examiner can be reached Monday-Friday from 8:30-6:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Woodward can be reached at (703) 308-4028.

Papers related to this application may be submitted to Group 1631 by facsimile transmission. Papers should be faxed to Group 1631 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 29, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist, whose telephone number is (703) 308-0196.

Nancy Ogihara
May 30, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER